

NEBRASKA'S HEALTH SCIENCE CENTER A Partner with Nebraska Health System PATHOLOGY AND MICROBIOLOGY

December 23, 2003

C. W. Jameson, Ph.D.Head, Report on CarcinogensNational Toxicology ProgramP.O. Box 12233Research Triangle Park, North Carolina 27709

Dear Dr. Jameson:

Thank you for the invitation to attend the meeting concerning the review process for listing and delisting chemicals on the report on carcinogens, to be held in Bethesda, January 27-28, 2004. Unfortunately, I am unable to attend that meeting, as I am attending another NTP meeting on the 29th of January, and have several other commitments that week that have to be taken care of.

I wish you a great deal of success in this review process, as it is an important topic for discussion. It is especially important that people understand the guidelines for what the criteria are for both listing and delisting chemicals. The experience that I had with respect to the delisting of saccharin was interesting and educational. It is my impression that the process has been improved since that time.

The major point that I would like to emphasize in the entire process, whether listing or delisting, is that all of the data that is available be included in the review. It is especially important to take into account dose response, exposure, and especially information regarding mechanism. Ultimately, it is only on the basis of mechanistic understanding that we can evaluate properly the implications of the animal studies with respect to their relevance to humans. I would like to note the recent publication in Critical Reviews in Toxicology (Issue 6, 2003), which presents the results of a panel of academicians, industry scientists, and government scientists in developing a framework for the evaluation of human relevance, based on mode of action data from animals. I believe that this framework can be helpful in evaluating chemicals with respect to listing or delisting on the report of carcinogens.

I wish you the very best in the new year, and much success with the continued process of the report on carcinogens.

Sincerely yours,

Samuel M. Cohen, M.D., Ph.D.

Professor and Chair, Pathology and Microbiology

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